

IN THE SPECIFICATION:

Please amend paragraph [0001] as follows:

**Field of the Invention**

[0001] ~~Field of the Invention:~~—The present invention relates generally to apparatus for use in noninvasively measuring hematocrit and, more specifically, to apparatus which are configured to effect electrical impedance and pressure plethysmography techniques to noninvasively measure hematocrit. The present invention also relates to methods for manufacturing and using the components of the hematocrit measurement apparatus.

Please amend paragraph [0002] as follows:

**Background of Related Art**

[0002] ~~Background of Related Art:~~ The “hematocrit” of blood, which is defined as the percentage of whole blood volume occupied by erythrocytes (*i.e.*, red blood cells), is an important measure of patient well-being in cases of trauma, blood loss by disease, iron depletion in pregnancy, dietary iron deficiency, and a number of more specific medical conditions.

Please amend paragraph [0005] as follows:

[0005] It has long been recognized by biomedical researchers that the electrical impedance of blood varies with hematocrit and that, as a result of this relationship, it should be possible to derive hematocrit from the measurement of blood impedance. Hematocrit has been successfully determined by measuring the impedance of blood that has been extracted from the patient and placed in an impedance measuring cell of controlled dimensions, where a fixed volume of the blood is contained, maintained at a known temperature, and agitated to maintain uniform cell distribution. Examples of such successful measurements are given by Okada and Schwan in “An Electrical Method to Determine Hematocrits,” IRE Transactions in Medical Electronics, ME-7:188-192 (1960) and by deVries et al. in “Implications of the Dielectrical Behavior of Human Blood for Continuous Online Measurement of Hematocrit,” Medical & Biological Engineering and Computing, pages 445-448 (1993) (hereinafter “deVries”). Like the centrifugal methods, these methods are invasive, however, and thus do not satisfy the need for a

~~non-invasive~~ noninvasive hematocrit measurement. The impedance methods have, however, provided the inspiration for some ingenious inventions to measure hematocrit ~~in vivo and non-invasively.~~ in vivo and noninvasively.

Please amend paragraph [0021] as follows:

[0021] ~~As an~~ An example of the use of interface unit includes assembling four electrodes with the interface unit such that the connection between the electrical contact of each electrode and its corresponding contact of the interface unit is sufficient to facilitate electrical communication therebetween. In addition, the elongate element of each electrode is positioned so as to be located at least partially within the receptacle of the interface unit. The elongate elements of the electrodes may be arranged so that the conductive coating layers thereof will contact desired portions of a body part to be introduced into the receptacle. The body part of a subject may then be introduced into the receptacle in such a way that the conductive coating layers of the elongate elements of the electrodes are in contact therewith. Thereafter, additional contact may be established between the conductive coating layer on remaining portions of the elongate elements and the body part of the subject. Noninvasive measurement of the hematocrit of the subject, as known in the art, may then commence.

Please amend paragraph [0058] as follows:

[0058] Elongate elements 14a and 14b of electrode pairs 10A, 10B, 10C, etc., and 10A', 10B', 10C', etc., of both rows 42 and 44, ~~respectively~~ respectively, are formed centrally along the length of strip 40. Elongate elements 14a and 14b of electrode pairs 10A, 10B, 10C, etc., of one row 42 mesh, or are interleaved with, elongate elements 14b and 14a of electrode pairs 10A', 10B', 10C', etc., that are located in the other row 44. Thus, an elongate element 14a of each electrode pair 10A', 10B', 10C', etc., 10A, 10B, 10C, etc., of row 44, 42 is located between elongate elements 14a and 14b of each electrode pair 10A, 10B, 10C, etc., 10A', 10B', 10C', etc., of row 42, 44. In addition, elongate elements 14b and 14a of adjacent electrode pairs 10A, 10B, 10C, etc., 10A', 10B', 10C', etc., in the same row 42, 44 are

separated are from one another by elongate elements 14b and 14a of electrode pairs 10A', 10B', 10C', etc., 10A, 10B, 10C, etc., of the other row 44, 42.

Please amend paragraph [0072] as follows:

[0072] Monitoring element 90 is disposed on upper surface 64 of base 60. Monitoring element 90 includes two sides 94 and 98, which protrude generally upwardly from upper surface 64 of base 60. Each side 94, 98 forms a half 92a, 92b of receptacle 92. Second end 84 of conduit 80 (FIGs. 7 and 8) is exposed to receptacle 92, for example, between sides 94 and 98, and may include a hose barb 85 of a known type disposed therein. Halves 92a and 92b of ~~receptacle~~ receptacle 92 are configured to, in combination, receive at least a portion of a body part of a subject, such as a human finger. Each side 94, 98 also includes an upper edge 97, 101, respectively. Corresponding ends 95, 99 and 96, 100 of sides 94 and 98 respectively form a front 102 and a rear 103 of monitoring element 90.

Please amend paragraph [0074] as follows:

[0074] Each contact receptacle 105 is configured to receive and retain a corresponding contact 107, which, in turn, is coupled to a corresponding electrical wire 88. Each contact 107 may be retained within its corresponding ~~receptacle~~ contact receptacle 105 with an adhesive material or mechanically (*e.g.*, by way of the depicted retaining ledge 106, which covers a circumferential ledge 108 and laterally surrounds a protruding element 109 of contact 107), as known in the art.

Please amend paragraph [0080] as follows:

[0080] Monitoring element 90 may be permanently coupled to cover 120 (~~FIG.~~ FIGs. 13 through 15). By way of example only, monitoring element 90 may be configured for hinged attachment to corresponding features of cover 120. In this regard, sides 94 and 98 of monitoring element 90 may include aligned apertures 118 and 119, respectively, formed longitudinally (relative to the orientation of base 60) therethrough to receive one or more hinge pins 135 (FIG. 13).

Please amend paragraph [0083] as follows:

[0083] Cover 120 may be secured in position relative to one or both of monitoring element 90 and base 60. In the example of cover 120 shown in FIGs. 13 through 15, two connection elements 136 and 137 protrude downwardly from sides 124 and 128, respectively, at or near a rear 133 of cover 120. Connection elements 136 and 137 are located in planes which are substantially parallel to a length of cover 120. Each connection element 136, 137 includes an aperture 138, 139, respectively, which is configured to align with a corresponding aperture 116, 117 (FIG. 10) of a side 94, 98 of monitoring element 90 and, thus, to mutually receive a hinge pin 135 that has also been disposed through its corresponding aperture 116, 117.

Please amend paragraph [0087] as follows:

[0087] As shown in FIGs. 13 through 16, when cover 120 is in a closed position over monitoring element 90, actuator handle 142 of locking element 140 may be biased toward rear 133 of cover 120 and rear 103 of monitoring element 90. As actuator handle 142 is moved in this fashion, locking arms 144 and 145 slide through their respective conduits 125 and 129 and the ends 144E, 145E of locking arms 144 and 145 are introduced into apertures 116 and 117 of monitoring element 90, thereby locking cover 120 into a closed position over monitoring element 90. When opening of cover 120 is desired, actuator handle 142 of locking element 140 may be pulled away from rear 133 of cover, thereby moving locking arms 144 and 145 in the reverse direction through conduits 125 and 129 and out of apertures 116 and 117 of monitoring ~~element.~~ element 90.

Please amend paragraph [00102] as follows:

[00102] Once electrode pairs 10 have been properly positioned, a body part of a subject, such as the illustrated human finger F, may be introduced into receptacle 92, as shown in FIG. 22. The body part may be introduced into receptacle 92 in such a way that each electrode ~~pair~~ pair 10 is located between the body part and monitoring element 90 and that a conductive coating layer 28 of each electrode pair 10 contacts the body part.

Please amend paragraph [00108] as follows:

[00108] In system 200, interface unit 50 communicates with an alternating current generator 205 which, which may be set to deliver a constant current having a waveform combining a low frequency (*e.g.*, about 10 kHz to about 200 kHz) with a high frequency (*e.g.*, about 2 MHz to about 10 MHz) to the outermost contacts 107 shown in FIG. 20 and, thus, to the outermost electrodes 11a and 11b shown in FIG. 21. The inner pair of electrodes 11b and 11a shown in FIG. 21 are connected to the input of a high impedance voltage amplifier 206, which senses the voltage between these electrodes. Both the current generator 205 and the amplifier 206 are connected to a processing element 207 (*e.g.*, a processor, computer or other group of processors, etc., which may be part of or associated with a computing system).

Please amend paragraph [00111] as follows:

[00111] A calibration device 214 may also communicate pneumatically with pressurization component 160 (FIG. 20). Calibration device 214 is configured to cause ~~pressurization component~~ component 160 to apply a precisely known amount of positive pressure to a portion of a body part located within receptacles 92 and 122 (FIGs. 5 and 23) to facilitate calibration of a pressure change that corresponds to a given volume. Calibration device 214 may be as simple as a small calibrated medical syringe, as depicted, which can be manually operated, or it may be a more complex device, controlled by the processing element 207 and capable of producing precise volume pulses of close to the same magnitude as the cardiac pulses for dynamic calibration.

Please amend paragraph [00112] as follows:

[00112] Once the subject's hematocrit has been measured, the body part (*e.g.*, finger F) may be removed from interface unit 50. For example, the process that has been described above in reference to FIGs. 5, 22, and 23 may be reversed. Thereafter, electrode ~~pairs~~ pairs 10 (FIG. 21) and/or pressurization components 160 may be removed from interface unit 50, making way for replacement electrode pairs 10 or pressurization components 160, which may be used to noninvasively measure the hematocrit of another subject.